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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	5
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Complete if Known

<i>Application Number</i>	10/600,266
<i>Filing Date</i>	June 20, 2003
<i>First Named Inventor</i>	Fumitoshi Asai
<i>Art Unit</i>	1614
<i>Examiner Name</i>	Brian Yong S. Kwon
<i>Attorney Docket Number</i>	17620-105003

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2005/0203122	09-15-2005	Doser et al.	
		2008/0300409	12-04-2008	Finkelstein et al.	
		2008/0306268	12-11-2008	Finkelstein et al.	
		2009/0187022	07-23-2009	Finkelstein et al.	

FOREIGN PATENT DOCUMENTS

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Sheet 2 of 5

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Art Unit	1614
Examiner Name	Brian Yong S. Kwon
Attorney Docket Number	17620-105003

NON PATENT LITERATURE DOCUMENTS

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		Aino Lepantalo, "Individual Variation in <i>in vitro</i> Efficacy of Antiplatelet Medication," Dissertation, 2007	
		Akyuz et al., "The effect of aspirin, ticlopidine and their low-dose combination on platelet aggregability in acute ischemic stroke: a short duration follow-up study," <i>Eur. J. Neurol.</i> , 6(1):57-61 (1999)	
		Alexander et al., "Prior Aspirin Use Predicts Worse Outcomes in Patients with Non-ST-Elevation Acute Coronary Syndromes," <i>The American Journal of Cardiology</i> , 84: 1147-1151, April 15, 1999	
		Antman et al., "Early and Late Benefits of Prasugrel in Patients with Acute Coronary Syndromes Undergoing Percutaneous Coronary Intervention," <i>Journal of American College of Cardiology</i> , 51(21):2028-2033, November 21, 2008	
		"Aspirin Ineffective for Primary Prevention in Patients with Diabetes," <i>MeReC Monthly No. 9</i> , December 2008, < http://www.npc.co.uk/ebt/merec/cardio/diabetes2/merec_monthly_no9.html >	
		Chapter 52 of <u>Heart Disease</u> , 6 th ed., by Goldhaber, pages 1902-1903, 2001	
		Clagette et al., "Prevention of Venous Thromboembolism," <i>Chest</i> , 114: 531S-560S (1998)	
		Clarke et al., "The Metabolism of Clopidogrel is Catalyzed by Human Cytochrome P450 3A and is Inhibited by Atorvastatin," <i>The American Society for Pharmacology and Experimental Therapeutic</i> , 31(1):53-59, 2003	
		"Collaborative Meta-Analysis of Randomised Trials of Antiplatelet Therapy for Prevention of Death, Myocardial Infarction, and Stroke in High Risk Patients," <i>BMJ</i> , 324:71-86; January 12, 2002	
		CURE Trial Investigators, "Effects of Clopidogrel in Addition to Aspirin in Patients with Acute Coronary Syndromes without ST-Segment Elevation," <i>NEJM</i> , 345(7):494-502 (2001)	
		CURE Study Investigators, "The Clopidogrel in Unstable angina to prevent Recurrent Events (CURE) trial programme: Rationale, design and baseline characteristics including a meta-analysis of the effects of thienopyridines in vascular disease," <i>Eur. Heart Journal</i> , 21(24):2033-2041 (December 1, 2000)	

Examiner Signature	Date Considered
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First Named Inventor	Fumitoshi Asai
Art Unit	1614
Examiner Name	Brian Yong S. Kwon
Attorney Docket Number	17620-105003

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		Erlinge et al., "Patients with Poor Responsiveness to Thienopyridine Treatment or With Diabetes Have Lower Levels of Circulating Active Metabolite, but their Platelets Respond Normally to Active Metabolite Added Ex Vivo," Journal of American College of Cardiology, 52(24):1968-1977, November 24, 2008	
		Farrell et al., "The lack of augmentation by aspirin of platelet reactivity by ticlopidine," Am J Cardiol., 83(5):770-774 (1999)	
		Fayer et al., "Interactions of Two Major Metabolites of Prasugrel, A Thienopyridine Antiplatelet Agent, With the Cytochromes P450," The American Society for Pharmacology and Experimental Therapeutics, 34(4):600-607, 2006	
		Ferguson et al., "Aspirin and Clopidogrel Response Variability," Texas Heart Institute Journal, 35(3):313-320, November 3, 2008	
		Henke, P.K., "Commentary," Perspectives in Vascular Surgery and Endovascular Therapy, 20(2):223-224 (2008)	
		Jaremo et al., "Individual Variations of Platelet Inhibition after Loading Doses of Clopidogrel," Journal of Internal Medicine, 252: 233-238, 2002	
		Lau et al., "Contribution of Hepatic Cytochrome P450 3A4 Metabolic Activity to the Phenomenon of Clopidogrel Resistance," Circulation, 109(2):166-171, January 20, 2004, Abstract only	
		Lipton et al., "Adjuvant antiplatelet therapy with aspirin in colo-rectal cancer," J. Med. 13(5-6): 419-429, 1982	
		Murphy et al., "Reduction in Recurrent Cardiovascular Events with Prasugrel Compared with Clopidogrel in Patients with Acute Coronary Syndromes from the TRITON-TIMI 38 Trial," European Heart Journal, 29:2473-2479, 2008	
		Payne et al., "Increased Active Metabolite Formation Explains the Greater Platelet Inhibition with Prasugrel Compared to High-Dose Clopidogrel," J. Cardiovasc. Pharmacol., 50(5):555-562, November 2007	
		Payne et al., "Switching Directly to Prasugrel from Clopidogrel Results in Greater Inhibition of Platelet Aggregation in Aspirin-Treated Subjects," Platelets, 19(4):275-281, June 2008	
		"Platelet Aggregation in Cancer," J. Biol. Chem, 2007, abstract 282, 25993-26001	
		Prescribing Label for Lovenox approved by the FDA on November 17, 2000	
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First Named Inventor	Fumitoshi Asai
Art Unit	1614
Examiner Name	Brian Yong S. Kwon
Attorney Docket Number	17620-105003

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		<p>Presentation to the Cardiovascular and Renal Drugs Advisory Committee, February 3, 2009, Slide # 26 http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm125999.htm</p> <p>Reinhart et al., "Prasugrel: A Critical Comparison with Clopidogrel," <i>Pharmacotherapy</i>, 29(12):1441-1451, 2009</p>	
		<p>Response to Notices of Opposition for European Patent No. 1 350 511, which issued from European Application No. 01271850.8, dated March 26, 2010</p> <p>Response to the Submission of the Patent Proprietor (Daiichi, Ube) of March 26, 2010 for European Patent No. 1 350 511, which issued from European Application No. 01271850.8, dated June 9, 2010</p> <p>Reuters Health Information, "Clopidogrel Resistance Does not Predict Response to Ticlopidine," <i>J. Am. Coll. Cardiol.</i>, 50:1132-1137, 2007</p>	
		Thebault et al., "Repeated-Dose Pharmacodynamics of Clopidogrel in Healthy Subjects," <i>Seminars in Thrombosis and Hemostasis</i> , 25(2): 9-14, 1999	
		Uzun et al., "The effects of heparin on DLD-1 colon cancer cell line," <i>Bratisl Lek Listy</i> , 110(1), 3-6, 2009	
		Wallentin et al., "Prasugrel Achieves Greater and Faster P2Y ₁₂ Receptor-Mediated Platelet Inhibition than Clopidogrel due to More Efficient Generation of Its Active Metabolite in Aspirin-Treated Patients with Coronary Artery Disease," <i>European Heart Journal</i> , 29:21-30, 2008	
		Wiviott et al., "Greater Clinical Benefit of More Intensive Oral Antiplatelet Therapy with Prasugrel in Patients with Diabetes Mellitus in the Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-Thrombolysis in Myocardial Infarction 38," <i>Circulation</i> , 1626-1636, October 14, 2008	
		Wiviott et al., "Intensive Oral Antiplatelet Therapy for Reduction of Ischaemic Events Including Stent Thrombosis in Patients with Acute Coronary Syndromes Treated with Percutaneous Coronary Intervention and Stenting in the TRITON-TIMI 38 Trial: a Subanalysis of a Randomised Trial," <<www.theLancet.com>>, 1-11, March 29, 2008	
		Wiviott et al., "Prasugrel Compared with High Loading-and Maintenance-Dose Clopidogrel in Patients with Planned Percutaneous Coronary Intervention," <i>Circulation</i> , 2923-2932, December 2007	

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Sheet 5 of 5

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Examiner Name	Brian Yong S. Kwon
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		Wiviott et al., "Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes," The New England Journal of Medicine, 357(20): 2002-2015, November 15, 2007	
		Wiviott et al., "Randomized Comparison of Prasugrel (CS-747, LY640315), a Novel Thienopyridine P2Y ₁₂ Antagonist, With Clopidogrel in Percutaneous Coronary Intervention," Circulation, 3366-3373, June 28, 2005	
		Worrall et al., "Antiplatelet Therapy in Secondary Stroke Prevention," <u>Current Atherosclerosis Reports</u> , 2(2):104-109 (March 2000)	
		Yende et al., "Effect of clopidogrel on bleeding after coronary artery bypass surgery," <u>Crit. Care Med.</u> , 29(12):2271-2275 (2001)	

Examiner Signature	/Brian-Yong Kwon/	Date Considered	08/12/2010
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